

Notice of Allowability

Application No.

10/644,418

Examiner

Eric S. Olson

Applicant(s)

SANDERS ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's amendment submitted June 12, 2007.
2. ☒ The allowed claim(s) is/are 1-8, 14-20 and 26-84.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date March 21, 2007
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The **claims** are amended as follows:

Withdrawn claims 9-13 and 21-25 are cancelled.

A period is inserted at the end of claim 1. The last line of claim 1 now reads, "a pharmaceutical composition thereof."

The **abstract** is amended as follows:

The last sentence of the abstract is amended to read: "Also provided is a method for inducing apoptosis in a cell comprising administering a composition comprising a compound having said structural formula."

The first paragraph of the **specification** is amended as follows:

This application is a divisional of pending U.S. Serial No. 09/502,592, filed February 11, 2000, issued as U.S. 6,770,672 on August 3, 2004, which is a continuation-in-part of U.S. Serial No. 09/404,001, filed September 23, 1999, issued as U.S. 6,417,223 on July 9, 2001, which claims benefit of provisional application U.S. Serial No. 60/101,542, filed September 23, 1998, now abandoned.

Detailed Action

This application is a divisional application of 09/502592, filed February 11, 2000, now US patent 6770672, which is a continuation in part of US application 09/404001, filed September 32, 1999, now US patent 6417223, which claims benefit of provisional application 60/101542, filed September 23, 1998. Claims 1-8, 14-20, and 26-84 are pending in this application and examined on the merits herein. Applicant's amendment submitted June 12, 2007 is acknowledged wherein claims 1, 2, 8, 20, 26, 27, 31, 49, 58, and 76 are amended.

The terminal disclaimers filed on June 12, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US patent 6654998 or any patent granted on copending application 10/695275, have been reviewed and is accepted. The terminal disclaimers have been recorded.

Applicant's arguments, submitted June 12, 2007, with respect to the rejection of instant claims 1-8, 14-20, and 26-84 under 35 USC 112, first paragraph, for lacking enablement for all types of cancer, has been fully considered and found to be persuasive to remove the rejection in view of the range of cell lines against which the claimed compounds have been tested. Therefore the rejection is withdrawn.

Applicant's terminal disclaimer, submitted June 12, 2007, has been fully considered and found persuasive to overcome the rejection of instant claims 1-8, 4-20,

and 26-84 under the doctrine of obviousness-type double patenting as being not patentably distinct from claims 1-16 of US patent 6654998. Therefore the rejection is withdrawn.

Applicant's terminal disclaimer, submitted June 12, 2007, has been fully considered and found persuasive to overcome the rejection of instant claims 1-8, 4-20, and 26-84 under the doctrine of obviousness-type double patenting as being not patentably distinct from claims 1-65 of copending application 10/695275. Therefore the rejection is withdrawn.

The reasons for allowance will be discussed below.

The reasons for allowance are as follows:

Reasons for Allowance

Claims 1-8, 14-20, and 26-84 are pending in this application and have been examined on the merits herein.

The claimed therapeutic methods for treating cell proliferative disorders and inducing apoptosis in cells, are not seen to be taught or fairly suggested by the prior art, and are directed to subject matter adequately described and enabled by Applicant's specification. For example, the synthetic methods on pp. 23-84 teach how to make the claimed invention and the methods and experimental data in examples 6-19 on pp. 86-111 disclose how to use the claimed invention. Although the range of cell proliferative

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conditions treated with the claimed method is very broad, the experimental data provided, particularly the data on apoptosis induction in a wide variety of cell lines provided in tables 1 and 2 in pp. 89 and 90, are sufficient to enable one skilled in the art to practice the claimed invention for a wide range of cell proliferative disorders. In particular, the cell lines tested are derived from a wide variety of tissues and are similar in breadth to those used by the National Cancer Institute to assess the anticancer activity of test compounds.

The claimed therapeutic methods are not taught or fairly suggested by the prior art. The closest prior art, for example, is represented by the references Della Valle et al., Lane et al., and Schneider et al. (US patents 5480645, 5915818, and 5780445, respectively, all cited in PTO-892) These prior art references all teach methods of using tocopherol or tocotrienol derivatives similar to those of the claimed invention for the treatment of cell proliferative disorders. However, none of these references disclose any compounds falling within the claimed invention. For example, The compounds of Della Valle et al. incorporate a hydroxylamine functionality as an essential feature, while those of the claimed invention do not. Those of Lane et al. (column 6, line 30 – column 7 line 52) do not include the specific ether or alkylamino substituents at the position R2 (R1 in the instant claims) that are included in the limitations of the claimed invention. Those of Schneider et al. possess glycosides at position R1 instead of the specific substituents recited in the instant claims. One of ordinary skill in the art would not have been motivated to modify any of these compounds in such a way as to arrive at the claimed compounds. In particular, the group R1 in the instant claims is defined to

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incorporate certain specific carboxyalkyl, hydroxyalkyl, and aminoalkyl substituents that would not have been obvious variations of the prior art.

Although the claimed invention is not patentably distinct from that claimed in US patent 6654998 and US patent application 10/695275, Applicant's terminal disclaimers filed June 12, 2007 are sufficient to overcome any double patenting rejections made over these patents.

In view of the information discussed above, the indicated subject matter is allowable over the prior art.

Accordingly, Applicant's amendment submitted June 12, 2007, and the accompanying examiner's amendment, are sufficient to remove all rejections made in the prior office action as discussed above and to place the application in condition for allowance.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled, "Comments on Statement of Reasons for Allowance."


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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